

# AHPA REPORT

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## Inside AHPA

### AHPA issues cannabis oversight recommendations for regulators

*Oversight framework promotes best practices for cannabis production and distribution from seed to consumption*

The American Herbal Products Association (AHPA) has published recommendations for regulators to address issues related to the safe use and responsible commerce of legally marketed products derived from *Cannabis* species.

Several states, including Illinois, Massachusetts, Nevada, and Oregon, have considered [AHPA's recommendations](#) in the development of state medical marijuana program regulations. AHPA's recommendations are also the foundational documents for the Americans for Safe Access Patient Focused Certification program, a third-party certification program that helps ensure the quality and consistency of medical marijuana products and services.

The legal status of *Cannabis* spp. products is in a transitional phase, with many states now allowing these products for medical or adult use. AHPA chartered a [Cannabis Committee](#) in 2010 to address issues created by the legalization of cannabis in a growing number of states.

"AHPA encourages regulatory authorities in states and municipalities where use of cannabis is allowed under local law to adopt these recommendations in order to promote the responsible commerce of this important botanical," said AHPA Cannabis Committee chair Tim Smale, founder and executive director of the nonprofit Remedy Compassion Center in Maine. "These best-practice recommendations provide a framework for the oversight of cannabis production and distribution practices from seed to consumption."

AHPA developed the following recommendations to address four operational stages of cannabis production and distribution:

1. [Cultivation and processing operations](#) addresses cultivation

practices, facility requirements, management of water resources, recordkeeping, and information disclosure. It also establishes best practices for operations that provide post-harvest processing of cannabis for distribution to dispensing operations or to manufacturing operations for the production of cannabis-derived products.

2. [Manufacturing and related operations](#) is generally modeled after federal current good manufacturing practice for foods and dietary supplements and focuses on personnel, product acquisition, physical plant and grounds, relevant controls, recordkeeping, and other factors that contribute to best practices in these operational settings.
3. [Laboratory operations](#) is a complement to existing good laboratory practices. These recommendations focus on the personnel, security, sample handling and disposal, and data management and reporting activities that may be unique to laboratories analyzing cannabis samples.
4. [Dispensing operations](#) focuses on personnel, security, product acquisition, recordkeeping, customer policies, and other matters that can contribute to best practices in the dispensary setting.

These recommendations are presented in the form of draft regulations to facilitate adoption and implementation. Regulatory authorities can consider the adoption of these recommendations, in whole or in part, as the basis for developing jurisdiction-specific regulations.

### AHPA grows more than 12% in 2014

*AHPA welcomes 17 new members this quarter*

AHPA, the global trade association and voice of the herbal products industry, has added 17 new members during the third quarter, for a total of 45 new member companies joining in 2014—a 12 percent increase in membership this year.

The *AHPA Report*, the official voice of the American Herbal Products Association (AHPA), is published monthly as a service to AHPA members and friends of the herbal products industry. The material contained in this publication is for the information of AHPA members. Although the information is believed to be correct, AHPA disclaims all responsibility for any damage or liability that may result from any reliance on the information contained in this publication.

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## FDA, FTC, PATENT, TRADEMARK & LICENSING COUNSEL SAFEGUARDING YOUR BUSINESS

### ***Proven Success in the Patent Office Trials***

In June of 2014, Amin Talati secured the invalidation of all 58 of the patent claims challenged for natural ingredient supplier Gnosis SpA against Merck & Cie and the South Alabama Medical Science Foundation by the United States Patent Trial and Appeal Board. The four at-issue patents relate to compositions including a natural active metabolite of folate used to treat folate deficiencies.

In this first dietary supplement *inter partes* review to go to final opinion, the U.S. Patent and Trademark Office found that many claims were unpatentable as obvious and canceled others at the request of Merck or SAMSF. *See*, Case Nos. 2013-IPR-00116, -117, -118 and -119.

Since its inception in September 2012, the *inter partes* review has offered a faster and less expensive way to challenge a patent's validity. Within the dietary supplement industry, this legal tool could help to solve some of the biggest challenges facing those accused of infringement.

### ***Proven Success at the U.S. International Trade Commission***

In June of 2013, Amin Talati defended its client and natural ingredient supplier Gnosis SpA and forced its opponents Merck & Cie, PamLab LLC and the South Alabama Medical Science Foundation to withdraw all patent infringement claims against Gnosis SpA prior to trial resulting in a final termination of the ITC investigation styled *Certain Reduced Folate Nutraceutical Products and L-methylfolate Raw Ingredients Used Therein*, Case No. 337-TA-857, in the U.S. International Trade Commission.

### ***Proven Success in the Federal Courts***

In defense of a patent infringement claim, Amin Talati persuaded the United States District Court for the Eastern District of Texas to invalidate certain patent claims asserted by Iovate Health Sciences, Inc. and the University of Florida Research Foundation, Inc. In obtaining this successful ruling for its client Bio-Engineered Supplements and Nutrition, Inc. (aka BSN), Amin Talati convinced the Court to rule that patent claims covering the use of nutritional supplements containing a ketoacid and an amino acid were invalid as anticipated by advertisements in *Flex* magazine before the critical date. In 2009, the Court of Appeals for the Federal Circuit affirmed this decision as correct.



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AHPA's newest members represent diverse sectors of the botanical industry, including herbal ingredient suppliers, international retailers and contract manufacturers, product distributors, analytical laboratories, industry service providers, and companies pioneering the burgeoning medicinal cannabis industry.

"AHPA members clearly understand the benefits of membership of our organization and the need to work together," said Michael McGuffin, AHPA president. "Those benefits include everything from networking, keeping abreast of current trends and events, self-regulation, and advocacy for critical policy issues and education."

New AHPA members include:


- **Amway**, one of the world's largest direct-selling businesses, offers consumer products and business opportunities supported by a global agribusiness, manufacturing, and logistics supply chain
- **Botanical Legal Defense**, dedicated to fighting overreaching government criminalization of certain botanicals
- **Brooke Law Group**, a general civil litigation law firm that has a growing specialty niche in California civil cannabis law, including business formation, contracts, cannabis-related lawsuits, collective defense, and more
- **Buchanan Ingersoll & Rooney PC**, a full-service law firm with highly successful Food and Drug Administration (FDA) practice
- **Elite Bio Labs**, a contract manufacturer of dietary supplements
- **Five Flavor Herbs**, a manufacturer of high-quality herbal products that blend Western and Chinese traditions
- **Grimaldi Law Offices**, a provider of high-value, cost-effective litigation defense, compliance counseling, and advocacy services for businesses of all sizes facing chemical and product regulatory challenges
- **Grow Emerging Companies LLC**, a consulting firm that provides a range of expertise in obtaining government funding for emerging and established firms across the nation
- **Healthy Healing**, a natural products industry pioneer whose philosophy is based on a natural, holistic method of healing that helps people feel better through self-help information, diet, exercise, and natural supplements
- **Herb Lore International Inc.**, a parent company of Herb Lore Etheric Light Essentials, creates and manufactures organic and biodynamic herbal products
- **Kilpatrick Townsend & Stockton LLP**, a nationally recognized law firm providing FDA-regulated companies of all sizes with an integrated, efficient approach to navigating federal and state laws
- **Kiss Me Organics**, an importer, wholesaler, and retailer of organic herbal products
- **Madsen Consultants**, a Nevada-based analytical laboratory

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Proof of Quality for Markers



- [Medical Marijuana Institute](#), founded in 2013 to educate, advocate for, and support the medical marijuana industry
- [PlantaMex](#), a company incorporated in Mexico since 1982 that specializes in the international trade of aromatic and medicinal plants, seeds, spices, and extracts
- [PSC Distribution](#), the world's premiere distributor of a novel line of embryonic plant extracts
- [Stanley Brothers Social Enterprises Inc.](#), licensed by the Colorado Department of Agriculture for commercial hemp and research with registered proprietary hemp strains with the state

AHPA is comprised of more than 300 domestic and foreign companies doing business as growers, processors, manufacturers, and marketers of herbs and herbal products. Founded in 1982, AHPA's mission is to promote the responsible commerce of herbal products.

There are two categories of AHPA membership: Active Members are directly engaged in growing, supplying, importing/exporting, processing, manufacturing, or marketing herbs or other botanicals or herbal products; Associate Members are individuals and entities that provide services to active members, including researchers, educators, consultants, attorneys, health professionals, and the media.

For a complete list of AHPA member companies, visit [AHPA's online member directory](#). Additional information about joining AHPA is available online or by contacting [Haley Chitty](#) at 301.588.1171 x104.

## AHPA president provides supplement regulation compliance strategies

AHPA President Michael McGuffin on Sept. 23 provided an overview of supplement regulations and compliance strategies at the "Best Practices in QC, GMP for Dietary Supplements and Nutraceuticals Effective Compliance Seminar" in Salt Lake City.

McGuffin's presentation covered a wide range of supplement regulatory issues, from current good manufacturing practice (cGMP) requirements and Food and Drug Administration (FDA) inspections to responses to FDA inspections and warning letters. "The essence of cGMP is a production and process control system that is designed to ensure the quality of the dietary supplement," McGuffin said. "It is important to ensure the quality of the dietary supplement throughout the production and process control system. Quality cannot be tested into the product only at the end."

McGuffin reviewed the FDA inspection process and highlighted common observations that FDA officials include in warning letters. He also provided advice on responding to FDA inspections. "A response to FDA observations should be detailed and provide evidence of implementation," McGuffin said. "It should explain the procedure developed to address FDA's observation and provide evidence that the procedure is in effect and being followed."

## AHPA Updates for September 2014

A list of the *AHPA Updates* issued to AHPA members during the month of September.

- [Tampa Bay Newspapers publish AHPA letter correcting misinformation about supplement regulation](#)
- [AHPA membership increases more than 12 percent with 45 new members in 2014](#)
- [Combine the AHPA promo code with early-bird registration for big savings](#)
- [AHPA issues cannabis oversight recommendations for regulators](#)
- [AHPA President speaks at annual Health Concerns Symposium](#)
- [AHPA President provides supplement regulation compliance strategies at Effective Compliance Seminar](#)
- [USP extends \\$100 AHPA member discount for DNA Methods for QC of Botanical Products workshop](#)

McGuffin also stressed the importance of using FDA warning letters to learn about the issues that FDA looks for when inspecting a facility for cGMP compliance. He used examples from recent warning letters to highlight common issues that FDA observes during inspections.

The [compliance seminar](#) provided attendees with practical approaches for quality control and cGMP compliance for dietary supplements, nutraceuticals, and natural products.

[Slides from McGuffin's presentation](#) are available online.

## AHPA-ERB Foundation forms American Ginseng Advisory Panel

The American Herbal Products Association Foundation for Education and Research on Botanicals (AHPA-ERB Foundation) has established the American Ginseng Advisory Panel to represent the interests of researchers, educators, and harvesters. The advisory panel was formed to provide expertise on the development and maintenance of regional and national collections of plant material that will preserve the genetic diversity of wild American ginseng (*Panax quinquefolius*).

A germplasm collection, defined as the long-term storage of hereditary plant material (i.e., seed), does not currently exist for American ginseng in the U.S. As demand for ginseng continues to rise, conservation through propagation becomes an important consideration and a valuable economic opportunity for cultivators of woods-grown and wild-simulated American ginseng. Germplasm collections ensure the

genetic variation of a plant species and also provide genetic resources for future research and *in situ* conservation opportunities.

Development of a national American ginseng germplasm collection is now in a preliminary planning stage under the direction of Dr. Joe-Ann McCoy at the North Carolina Arboretum. The national program will entail the identification, collection, and propagation of a significant number of genetically diverse populations of *Panax quinquefolius* sustainably collected from multiple locations within its native range in the U.S. McCoy is also initiating a regional American ginseng germplasm collection for western North Carolina.

“Starting with a regional germplasm collection will provide a template for the broader project that encompasses the wide geographic range of this plant,” McCoy said. “The AHPA-ERB Foundation’s foresight and dedication to the long-term conservation of this precious species will help preserve the native populations for future generations.”

American ginseng is one of the most valuable North American wild-crafted non-timber plants and is traded principally in international markets. Primarily found in the Appalachian region of the U.S., native populations are subject to numerous pressures, including harvesting (if sustainable practices are not utilized), loss of habitat due to land development and mining, and deer browsing.

The advisory panel will also provide guidance on obtaining financial support and publication of research and other data generated during

establishment of the collections. The panel is composed of the following members:

- Eric Burkhart, Ph.D., program director, Plant Science, Penn State University
- Lyle Craker, Ph.D., professor, University of Massachusetts Amherst
- Jennifer Cruse-Sanders, Ph.D., vice president of science and conservation, Atlanta Botanical Garden
- Tony Hayes, president, Ridge Runner Trading Co.
- Gary Kauffman, botanist/ecologist, U.S. Forest Service
- Susan Leopold, Ph.D., executive director, United Plant Savers
- Allen Lockard, president, American Botanicals
- Joe-Ann McCoy, Ph.D., director, North Carolina Arboretum Germplasm Repository
- James McGraw, Ph.D., professor, West Virginia University
- Michael McGuffin, president, AHPA

In addition, Patricia Ford, a botanist with the U.S. Fish and Wildlife Service (USFWS), will serve as a liaison to the advisory panel. American ginseng is listed in Appendix II of the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), an international agreement to ensure that trade of certain plants and animals does not threaten their survival in the wild. USFWS regulates the export of American ginseng through the issuance of CITES permits to ensure that roots are legally and sustainably harvested.

“The harvest pressure on wild American ginseng and the disappearance of more and more of its natural habitat create a risk of the loss of the genetic diversity critical for the long-term health of the species,” said USFWS Director Dan Ashe. “Creating a seed bank for ginseng is vital to ensure the continued sustainability of this species, which plays an important role in the economy and culture of communities throughout the United States.”

The AHPA-ERB Foundation is a 501(c)(3) educational foundation established by the AHPA for the purpose of promoting education and research on medicinal, therapeutic, and health-promoting herbs. The foundation’s current and previous efforts have included providing funding for a multiyear study of the impact of wild collection on populations of osha (*Ligusticum porteri*), development of a guidance document on compliance with CITES for the natural products industry, and revision of AHPA’s *Botanical Safety Handbook, Second Edition*. For further information, please contact the foundation at [ahpafoundation@ahpa.org](mailto:ahpafoundation@ahpa.org).

The central mission of the North Carolina Arboretum, an affiliate institution of the 17-campus University of North Carolina system, is to cultivate connections between people and plants. Established in 1986 by the General Assembly as an affiliate of the University of North Carolina, the Arboretum was founded nearly a century after Frederick Law Olmsted, the “Father of American Landscape



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Architecture,” first envisioned such an institution near Asheville as part of his legacy to the Biltmore Estate. The North Carolina Arboretum is adjacent to the scenic Blue Ridge Parkway, and is located in one of the most beautiful natural settings in America. See [ncarboretum.org](http://ncarboretum.org) for more information.

## New members

### *Associate Members*

**Canna Group Inc.** is a leader in the huge and emerging cannabis market. CGI consults with, invests in, and mentors businesses to become successful in the cannabis industry.

**CannaLabs** is a marijuana testing facility located in Denver. We currently offer potency, residual solvent, microbiological, water activity, and pesticide testing, and will be adding more soon.

**Waters Corp.** designs, manufactures, sells, and services ultra-performance liquid chromatography (UPLC), high performance liquid chromatography (HPLC), chromatography columns and chemistry products, mass spectrometry (MS) systems, thermal analysis, and rheometry instruments.

## Savings opportunities for AHPA members

Within the pages of this edition of *AHPA Report*, we are pleased to provide our members with several valuable, money-saving opportunities. The following goods and services are offered at a discount for—or are uniquely available to—AHPA members this month:

- » AHPA's *Botanical Safety Handbook*, 25% off ([page 20](#))
- » American Herbal Pharmacopoeia, 10% off ([page 14](#))
- » CPG Jobs, 15% off for employers ([page 15](#))
- » The Tan Sheet, 20% off new subscriptions ([page 16](#))

## AHPA in the news

A monthly review of media mentions related to the American Herbal Products Association (AHPA) and/or AHPA staff.

- [AHPA-ERB Foundation forms ginseng advisory panel](#), Engredea News & Analysis
- [Know Your Trade Association: the American Herbal Products Association](#), Natural Products Insider
- [FDA's NDI Guidance—No Greater Controversy in DSHEA's 20 years](#), Natural Products Insider
- [Finding The Right Trade Association](#), Natural Products Insider
- [Which Are Emerging Adulterants in Sports Supplements?](#) Nutritional Outlook
- [AHPA-ERB Foundation Forms The American Ginseng Advisory Panel](#), Natural Products Insider
- [NewsBriefs: October 2014](#), WholeFoods Magazine
- [House Passes Designer Anabolic Steroid Control Act](#), WholeFoods Magazine
- [American Ginseng Advisory Panel formed to preserve the genetic diversity of wild botanical](#), NutraIngredients-usa.com
- [AHPA issues recommendations on cannabis regulation](#), NutraIngredients-usa.com
- [BI Nutraceuticals to Present on Botanicals at SupplySide](#), Natural Products Insider
- [AHPA grows membership by 12% as 45 companies join in 2014](#), NutraIngredients-usa.com
- [Negotiating the New Dietary Ingredient Process](#), Natural Products Insider
- [Class action against NBTY alleges protein-spiking](#), Legal News Line
- [AHPA issues cannabis oversight recommendations](#), Engredea News & Analysis
- [AHPA membership jumps 12% in 2014](#), Engredea News & Analysis





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## Special Topic

### The importance of reliable product chemistry data: A case study

by Dallas Wait, Ph.D., Gradient

Reliable and defensible data underpin the value and validity of decisions made by dietary supplement and food manufacturers, consumers, clinicians, researchers, and regulatory investigators. The measurement process used to obtain product chemistry data involves collecting representative samples, properly storing and processing the samples, analyzing the samples with validated test methods and defined quality-control criteria, and validating the results. Understanding the intricacies of the measurement process and any associated errors is key to the generation of accurate measurements that address the objectives of the study.<sup>1</sup>

The analytical activities associated with a measurement focus on two issues: identification and quantitation of an analyte. Demonstrating that a test method can provide reliable identification and reliable quantitation requires validation of the test method prior to sample analysis.<sup>2,3</sup> Researchers and end users of data often focus their attention on the quantitative aspects of the results, and they sometimes assume the identification of the analyte is reliable. This can be a critical mistake.

Case in point: There was a recent controversy regarding the constituents present in *Dendrobium*-based sports supplements.<sup>4</sup> The purpose of this article is not to weigh in on the toxicological, regulatory, and labeling debates, but instead to evaluate whether sound science has been used to characterize the alleged presence of diethyl-phenethylamine isomers in the supplements.

There are three structural (or constitutional) isomers of diethyl-phenethylamine pertinent to this ongoing controversy: N, $\alpha$ -diethyl-phenethylamine (N, $\alpha$  isomer), N, $\beta$ -diethyl-phenethylamine (N, $\beta$  isomer), and N,N-diethyl-phenethylamine (N,N isomer).

The resolution and identification of these three structural isomers should be unambiguous and reliable. The N, $\alpha$  and N, $\beta$  isomers have very similar chromatographic characteristics and are difficult to resolve unless the test method being used is optimized to properly separate both isomers. The resolution of the N,N isomer from the N, $\alpha$  or N, $\beta$  isomers is relatively easy to achieve.

At least three studies have characterized diethyl-phenethylamine constituents, two of those for *Dendrobium*-based supplements, one by an independent commercial laboratory,<sup>5</sup> one by an academic laboratory,<sup>6</sup> both of which reference the analysis of an unknown matrix by a Korean forensic laboratory.<sup>7</sup> Surprisingly, all three laboratories ignored the N, $\beta$  isomer in their studies, both in their LC/MS/MS procedure and their NMR spectroscopic analysis. As such, the alleged presence of the N, $\alpha$  isomer may actually be the N, $\beta$  isomer, or a combination of the two. Unequivocal identification of

the N, $\beta$  and N, $\alpha$  isomers is particularly critical since the N, $\beta$  isomer does not share the same structural similarities that N, $\alpha$  shares with methamphetamine (also alkylated in the  $\alpha$  position, not the  $\beta$  position). If the isomeric arrangement of atoms in a compound such as diethyl-phenethylamine does not align with a receptor site or enzyme, the biological activity associated with that compound can be affected, sometimes significantly.

There is an abundance of guidance concerning the importance of determining the selectivity/specificity for each target analyte as part of the method validation process. For instance, the findings of a bioanalytical method validation conference sponsored by the Food and Drug Administration and the American Association of Pharmaceutical Scientists<sup>8</sup> were summarized by Peters *et al.*<sup>9</sup> They state that selectivity, which must be considered in method validation, is “the ability of the bioanalytical method to measure unequivocally and to differentiate the analyte(s) in the presence of components, which may be expected to be present,” such as N, $\alpha$  and N, $\beta$  isomers of diethyl-phenethylamine.

The International Conference on Harmonization guidelines state, “Suitable identification tests should be able to discriminate between compounds of closely related structures which are likely to be present.” Further, “For critical separations, specificity can be demonstrated by the resolution of the two components which elute closest to each other.”<sup>10</sup> Since all three laboratory studies ignored the N, $\beta$  isomer, the alleged presence and quantitation of the N, $\alpha$  isomer is in doubt.

Recently a Swedish research laboratory validated a test method for all three diethyl-phenethylamine isomers in a *Dendrobium*-based supplement.<sup>11</sup> The researchers, using a UHPLC-MS/MS system, optimized the chromatographic resolution of their method, distinctly separating all three diethyl-phenethylamine isomers. Using their validated method, the researchers then analyzed some of the same *Dendrobium*-based dietary supplement products analyzed by two of the laboratories and found that the N, $\beta$  isomer predominated, by far (three orders of magnitude), over the N, $\alpha$  isomer. It appears that all three laboratories, which published their studies in peer-reviewed journals, may have mischaracterized the diethyl-phenethylamine content of the products they analyzed.

The revelation that three different laboratories ignored a fundamen-

Disclaimer: The information and opinions presented in this guest article are those of the author and do not necessarily reflect those of the American Herbal Products Association (AHPA) or its members. AHPA believes the information enclosed to be accurate, but does not ensure its accuracy. The content in this article is for general information purposes only.

tal tenet of analytical chemistry by not properly validating a test method prior to sample analysis should give data users pause. Guidance regarding how to acquire reliable analytical services has been provided elsewhere,<sup>12</sup> including from AHPA.<sup>13</sup>

Nonetheless, it is apparent that buyers of analytical services should request and review method validation studies prior to sample anal-

ysis involving new analytical methods or when an established method is going to be used to analyze a new matrix.

*Dr. Dallas Wait is a principal and product chemistry expert with Gradient and has consulted for a firm that has previously used Dendrobium as an ingredient in its products. He can be reached at 617.395.5527 or [dwait@gradientcorp.com](mailto:dwait@gradientcorp.com).*

## Endnotes

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## Gradient's Scientists Address Dietary Supplement Challenges



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## Legal and Regulatory

### FDA inspecting, warning, enjoining, prosecuting distributors of drug-spiked 'supplements'

by Anthony L. Young, Kleinfeld, Kaplan & Becker LLP and AHPA General Counsel

Drug-spiked "supplements" are the main driver behind calls for increased regulation of dietary supplements. However, Food and Drug Administration (FDA) enforcement may reduce the prevalence of such products in the marketplace.

Two recent warning letters, one to [West Coast Laboratories](#) and the other to [Human Science Foundation](#), allege that at least one "supplement" sold by these companies was drug-spiked. If the past is prologue, they can expect that FDA will promptly reinspect their facilities to assure that they are in compliance with current good manufacturing practice. If they are not compliant, they may end up like Mira Health Products of Farmingdale, N.Y. [Mira Health was enjoined from manufacturing dietary supplements](#) a year after being caught distributing a vitamin B product that contained two potentially harmful anabolic steroids: methasterone (a controlled substance) and dimethazine.

FDA is also prosecuting distributors of drug-spiked "supplements." One [case](#) involves a former U.S. Marshal who was distributing these

products using both his home and work computers. Other purveyors of "supplements" spiked with steroids that have been prosecuted include [Anabolic Resources Inc.](#); [Tribravus Enterprises LLC, dba IForce Nutrition](#); and [Myogenix Corp.](#) Others have been pinched for selling products containing [diuretics](#) and [sexual stimulant drugs](#). The fact that this is a risky business has become abundantly clear. FDA is not slapping companies and their officers on the wrist. The agency is hitting them hard.

At some point, we would expect to see some of those involved in the drug-spiked "supplement" trade to appear on the FDA Office of Criminal Investigations' [Most Wanted List](#). You can read the results of FDA's criminal investigation activities in the press releases found on its [website](#).

These are serious cases, and many involve criminals who create and distribute designer drugs. The biggest prosecution was of a ring of synthetic drug distributors, eight of whom were sentenced to four to 20 years. All were involved in the distribution of synthetic controlled substance analogues that led to the [deaths](#) of two teens.

The overall takeaway from the various FDA prosecutions is that counterfeit drugs are a continuing problem for the pharmaceutical industry, just as drug-spiked "supplements" are a problem for the dietary supplement industry.

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## Botanical Science Update

by Maged Sharaf, Ph.D.

### Newly designed ODS program website

- Newly designed ODS Dietary Supplement Analytical Methods and Reference Materials Program Website, U.S. Department of Health and Human Services NIH ODS, Sept. 24, 2014

The Dietary Supplement Analytical Methods and Reference Materials Program website of the Office of Dietary Supplements at the National Institutes of Health has been redesigned and updated. Among the new features is a search box to search the site by substance, plant, matrix, method, compound, etc., to locate published and available reference materials, methods, and resources.

### Effect of cruciferous and apiaceous vegetables on inflammation

- Sandi L. Navarro, Yvonne Schwarz, Xiaoling Song, Ching-Yun Wang, Chu Chen, Sabrina P. Trudo, Alan R. Kristal, Mario Kratz, David L. Eaton, and Johanna W. Lampe. [Cruciferous Vegetables Had Variable Effects on Biomarkers of Systemic Inflammation in a Randomized Controlled Trial in Healthy Young Adults.](#) *Journal of Nutrition*. DOI: 10.3945/jn.114.197434, Aug. 27, 2014

In a randomized, crossover trial involving 63 healthy men and women ages 20 to 40, consumption of cruciferous and apiaceous vegetables reduced the serum concentration of the inflammation biomarker interleukin-6. This effect was found to be genotype dependent. Results for other biomarkers of inflammation were not consistent.

### Cytoprotection of ginger constituent and metabolite

- Huadong Chen, Junsheng Fu, Hao Chen, Yuhui Hu, Dominique N. Soroka, Justin R. Prigge, Edward E. Schmidt, Feng Yan, Michael B. Major, Xiaoxin Chen, and Shengmin Sang. [Ginger Compound \[6\]-Shogaol and Its Cysteine-Conjugated Metabolite \(M2\) Activate Nrf2 in Colon Epithelial Cells in Vitro and in Vivo.](#) *Chemical Research in Toxicology*. DOI: 10.1021/tx5002145. Aug. 8, 2014

A bioactive compound isolated from ginger, 6-shogaol, and its cysteine-conjugated metabolite activate the nuclear factor erythroid 2-related factor 2 (Nrf2) in colon epithelial cells *in vitro* and *in vivo*. Activation of Nrf2 mediates multiple schemes of cytoprotection and delays in the aging process.



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## Phytochemicals to treat Alzheimer's disease

✿ Mi Hye Kim, Sung-Hoon Kim, Woong Mo Yang. [Mechanisms of Action of Phytochemicals from Medicinal Herbs in the Treatment of Alzheimer's Disease](#). *Planta Medica*. DOI: 10.1055/s-0034-1383038. August 2014

A review of literature and mechanisms of berberine, curcumin, ginsenoside Rg1, puerarin, and silibinin as alternative treatments for Alzheimer's disease. Sources cited are PubMed, ScienceDirect, and Google Scholar

## Anti-hepatitis B activities of niranthin from *Phyllanthus niruri*

✿ Sheng Liua, Wanxing Weia, Kaichuang Shib, Xun Caoa, Min Zhoua, Zhiping Liua. [In vitro and in vivo anti-hepatitis B virus activities of the lignan niranthin isolated from Phyllanthus niruri L.](#) *Journal of Ethnopharmacology*. DOI: 10.1016/j.jep.2014.05.064. Sept. 11, 2014

Hepatoprotective effect of niranthin, a lignan isolated from *Phyllanthus niruri*, was tested *in vitro* in human hepatitis B virus-transfected liver cell line and *in vivo* in ducklings infected with hepatitis B virus. "The experimental data demonstrated that niranthin exhibits anti-hepatitis B virus activity both *in vitro* and *in vivo*," the authors concluded.

## Inhibition of cytochrome p450 2c9 by allyl isothiocyanate

✿ Yun-Ping Lim, Wei-Cheng Chen, Ching-Hao Cheng, Wei-

Chih Ma, Yu-Hsien Lin, Cing-Yu Chen, Dong-Zong Hung, Jih-Jung Chen, Tsuyoshi Yokoi, Miki Nakajima, Chao-Jung Chen. [Inhibition of Cytochrome P450 2C9 Expression and Activity In Vitro by Allyl Isothiocyanate](#). *Planta Medica*. DOI: 10.1055/s-0034-1383000. January 2014

Allyl isothiocyanate, a hydrolysis product of the thioglucoside sinigrin, a constituent in cruciferous vegetables that is responsible for their pungent taste, was found *in vitro* to inhibit the expression and activity of cytochrome P450 2C9, an enzyme responsible for the metabolism of most nonsteroidal anti-inflammatory drugs, the active form of warfarin, and phenytoin. The authors of the study recommended making similar findings available to health care professionals.

## Blueberry powder increases natural killer cells, reduces arterial stiffness

✿ Lisa S. McAnulty, Scott R. Collier, Michael J. Landram, D. Stanton Whittaker, Sydeena E. Isaacs, Jason M. Klemka, Sarah L. Cheek, Jennifer C. Arms, and Steven R. McAnulty. [Six weeks daily ingestion of whole blueberry powder increases natural killer cell counts and reduces arterial stiffness in sedentary males and females](#). *Journal of Nutrition Research*. DOI: 10.1016/j.nutres.2014.07.002. July 10, 2014

Daily ingestion of blueberry powder equivalent to 250 grams of berries for six weeks reduced augmentation index, a surrogate measure of arterial stiffness; reduced aortic systolic pressures; reduced diastolic pressure in subjects with prehypertensive pressures; and increased natural killer cells. These were the findings of a study on 25 men and postmenopausal women ages 18 to 50.



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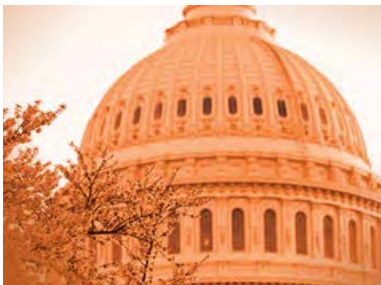
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## Calendar of Events

- ◆ [SupplySide West](#)  
Oct. 6 – 10 • Las Vegas, Nev.
- ◆ [12th Annual Restorative Medicine Conference](#)  
Oct. 9 – 12 • Santa Fe, N.M.
- ◆ [National Institute of Medical Herbalists 150th Annual Conference](#)  
Oct. 9 – 12 • Nottingham, England
- ◆ [American College of Nutrition's 55th Annual Conference](#)  
Oct. 15 – 18 • San Antonio, Texas
- ◆ [Shanghai International Conference on Traditional Chinese Medicine and Natural Medicine](#)  
Oct. 16 – 17 • Shanghai, China
- ◆ [BIT's 2nd Annual World Congress of Nutrition & Health](#)  
Oct. 24 – 26 • Tiyuan, China
- ◆ [11th International Symposium on Ginseng](#)  
Oct. 27 – 30 • Seoul, Korea
- ◆ [WFAS World Conference on Acupuncture and Integrative Medicine](#)  
Oct. 31 – Nov. 2 • Houston, Texas
- ◆ [American Herbalists Guild 25th Anniversary Symposium](#)  
Nov. 6 – 10 • Pine Mountain, Ga.
- ◆ [Fourth Annual Cancer Strategies Symposium](#)  
Nov. 7 – 10 • Phoenix, Ariz.
- ◆ [IUCN World Parks Congress](#)  
Nov. 12 – 19 • Sydney, Australia
- ◆ [International Congress of Ethnobotany](#)  
Nov. 17 – 21 • Cordoba, Spain
- ◆ [17th International Congress of FFC](#)  
Nov. 18 – 19 • San Diego, Calif.
- ◆ [5th International Conference on Plants & Environmental Pollution](#)  
Dec. 3 – 6 • Lucknow, India
- ◆ [4th Annual Conference & Expo for Integrative Therapies Institute](#)  
Jan. 23 – 25 • San Diego, Calif.
- ◆ [Mexican Healthy Products Summit](#)  
Jan. 23 – 25 • Puerto Vallarta, Mexico



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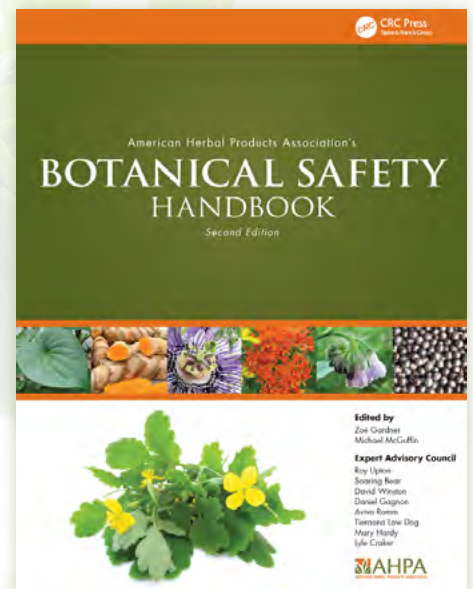
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